

Notice of Allowability	Application No.	Applicant(s)	
	10/620,049	HARVEY ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 29, 2004.
2. ☒ The allowed claim(s) is/are 1-21.
3. ☒ The drawings filed on 13 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/3/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

ALLOWANCE

1. This Office Action is responsive to Applicant's response October 29, 2004. All rejections of record are withdrawn in view of Applicant's amendment and remarks. Claims 1-21 are allowed.

2. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests an isolated antibody or fragment thereof that binds immunologically to *Bacillus anthracis* protective antigen with an affinity K_d of between about 140pM and about 21 pM as determined by surface plasmon resonance.

Examiner's Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Hanson on February 3, 2005.

- A. Authorization to cancel non-elected claims.
- B. The application has been amended as follows:

Art Unit: 1645

In the specification: at page 6, Brief Description of the Drawings:

At line 7, "FIG.2:" should be changed to ---FIGURES 2A-B---

At line 12 "FIG.3:" should be changes to ---FIGURES 3A-C---

At line 17, "FIG. 5:" should be changed to ---FIGURES 4A-B---

At line 22, "FIG.6:" should be changed to ---FIG.5."

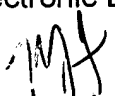
At line 24 "FIG.7:" should be changed to ---FIG.6:---


4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
February 3, 2005


Walter R. P. Smith
Supervisor of the Group
Biotechnology Patent Examiner
February 3, 2005

CLEAN COPY OF CLAIMS

1. An isolated antibody or fragment thereof that binds immunologically to *Bacillus anthracis* protective antigen with an affinity K_d of between about 140 pM and about 21 pM as determined by surface plasmon resonance.
2. The isolated antibody or fragment thereof of claim 1, further defined as binding immunologically to *Bacillus anthracis* protective antigen with a binding affinity K_d of between about 96 pM and about 21 pM.
3. The isolated antibody or fragment thereof of claim 1, further defined as binding immunologically to *Bacillus anthracis* protective antigen with a binding affinity K_d of between about 35 pM and about 21 pM.
4. The isolated antibody or fragment thereof of claim 1, further defined as a scAb, Fab or SFv.
5. The isolated antibody or fragment thereof of claim 1, further defined as comprising an Fc domain of 1gA, 1gD, IgE, IgG or 1gM.
6. The isolated antibody or fragment thereof of claim 1, further defined as a humanized antibody.

7. The isolated antibody or fragment thereof of claim 1, wherein the antibody is human.
8. The isolated antibody or fragment thereof of claim 1, comprising an scFv fragment and antibody constant regions forming a monovalent antibody portion of at least 40 kDa.
9. An isolated antibody or fragment thereof that binds immunologically to *Bacillus anthracis* protective antigen and comprises the variable light and variable heavy chain of SEQ ID NO:21, with the exception that the variable light and variable heavy chain collectively comprise at least three modifications selected from the group consisting of: I21V, S22G, L33S, Q38R, L46F, Q55L, S56P, T74A, S76N, Q78L, L94P, S7P, K19R, S30N, T57S, K62R, K64E, T68I, and M80L; wherein said I21V, S22G, L33S, Q38R, L46F, Q55L, S56P, T74A, S76N, Q78L and L94P are in the variable light chain and wherein said S7P, K19R, S30N, T57S, K62R, K64E, T68I and M80L are in the variable heavy chain.
10. The isolated antibody or fragment thereof of claim 9, further defined as comprising at least five of said modifications.
11. The isolated antibody or fragment thereof of claim 9, further defined as comprising all of said modifications.

12. The isolated antibody or fragment thereof of claim 9, further defined as binding immunologically to *Bacillus anthracis* protective antigen with an affinity K_d of between about 140 pM and about 21 pM as determined by surface plasmon resonance.

13. The isolated antibody or fragment thereof of claim 9, further defined as comprising Q551 and S56P.

14. The isolated antibody or fragment thereof of claim 9, further defined as comprising the variable light chain of SEQ ID NO:22 or SEQ ID NO:24.

15. The isolated antibody or fragment thereof of claim 9, further defined as comprising the variable heavy chain of SEQ ID NO:22 or SEQ ID NO:24.

16. The isolated antibody or fragment thereof of claim 9, further defined as comprising the variable light and variable heavy chains of SEQ ID NO:22.

17. The isolated antibody or fragment thereof of claim 9, further defined as comprising the variable light and variable heavy chains of SEQ ID NO:24.

18. The isolated antibody or fragment thereof of claim 7, further defined as a scAb, Fab or SFv.

19. The isolated antibody or fragment thereof of claim 7, further defined as comprising an Fc domain of IgA, IgD, IgE, IgG or IgM.

20. The isolated antibody or fragment thereof of claim 7, further defined as a humanized antibody.

21. The isolated antibody or fragment thereof of claim 1, comprising an scFv fragment and antibody constant regions forming a monovalent antibody portion of at least 40 Kda.